IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P., GALDERMA S.A. and GALDERMA RESEARCH AND DEVELOPMENT, S.N.C.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACTAVIS MID ATLANTIC LLC,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Galderma Laboratories, L.P., Galderma S.A., and Galderma Research and Development, S.N.C. (collectively "Galderma") file this Complaint for patent infringement against Actavis Mid Atlantic LLC ("Actavis"), and allege as follows:

JURISDICTION AND PARTIES

1. Plaintiff Galderma Laboratories, L.P. is a Texas limited partnership, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177. Galderma Laboratories, L.P. is engaged in the business of research, development, manufacture, and sale of dermatological and pharmaceutical products.

2. Plaintiff Galderma S.A. is a Swiss company having a principal place of business at World Trade Center, Avenue de Gratta-Paille 1, Case Postale 552, 1000 Lausanne 30 Grey. Galderma S.A. is engaged in the business of research, development, manufacture, and sale of dermatological and pharmaceutical products.

3. Plaintiff Galderma Research & Development, S.N.C. is a French company having a principal place of business at 2400 Route Des Colles, Les Templiers, 06410 Biot, France. Galderma Research & Development, S.N.C. is engaged in the business of research and

development of dermatological and pharmaceutical products. Galderma Research & Development, S.N.C. is the current owner of United States Patent Nos. 7,579,377 ("the '377 patent") and 7,737,181 ("the '181 patent").

4. On information and belief, Actavis is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960. Actavis is engaged in the manufacturing, offering for sale, and sale of generic pharmaceutical products. On information and belief, Actavis's products are marketed and sold for distribution in Delaware and throughout the United States.

5. The Court has personal jurisdiction over Actavis because Actavis is a Delaware company and has a registered agent in Delaware.

6. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.* This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT
(Infringement of the '377 Patent Under 35 U.S.C. § 271(e)(2))

7. Galderma realleges and incorporates by reference paragraphs 1-6.

8. The '377 patent, entitled "Administration of 6-[3-(1-adamantyl)-4methoxyphenyl]-2-naphthoic acid for the treatment of dermatological disorders," was duly and legally issued to inventors Michael Graeber and Janusz Czernielewski by the United States Patent and Trademark Office ("PTO") on August 25, 2009. The '377 is currently owned by Galderma Research & Development, S.N.C. and expires on February 23, 2025. This expiration date includes a 714-day patent term adjustment granted by the PTO pursuant to 35 U.S.C.

§ 154(b). A true and correct copy of the '377 patent is attached as Exhibit A. A true and correct copy of the Issue Notification reflecting the '377 patent term adjustment is attached as Exhibit B.

9. Galderma Laboratories, L.P. is the holder of New Drug Application ("NDA") No. 21-753 for the use of Differin® 0.3% gel in the topical treatment of *acne vulgaris*. The FDA approved NDA No. 21-753 on June 19, 2007. The '377 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-753.

10. Galderma manufactures and sells various dosage strengths of topical gels and cream containing the active ingredient 6-[3-(1-adamantyl)-4methoxyphenyl]-2-naphthoic acid (also known as "adapalene") in the United States under the brand name Differin®.

11. On information and belief, Actavis submitted or caused to be submitted to the FDA ANDA No. 201-000 under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of adapalene gel 0.3% ("Actavis's Adapalene Gel") in the United States before the expiration of the '377 patent.

12. On information and belief, ANDA No. 201-000 contains a Paragraph IV certification alleging that the claims of the '377 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, offer for sale or importation of the Actavis's Adapalene Gel prior to the expiration date of the '377 patent.

13. Actavis sent or caused to be sent to Galderma a letter dated September 28, 2010 ("the Notice Letter") notifying Galderma that Actavis had submitted ANDA No. 201-000, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Notice Letter alleges noninfringement of claims 1-3 of the '377 patent.

14. Under 35 U.S.C. § 271(e)(2)(A), Actavis infringed one or more claims of the '377 patent, in violation of Galderma's patent rights, by submitting to the FDA an ANDA that seeks approval to commercially market--before the expiration date of the '377 patent--Actavis's Adapalene Gel, the use of which would directly infringe one or more claims of the '377 patent, and the manufacture and sale of which would contribute to or induce the direct infringement of one or more claims of the '377 patent by users of Actavis's Adapalene Gel.

15. Upon information and belief, Actavis has also induced or contributed to, and will induce or contribute to, infringement of one or more claims of the '377 patent--in violation of Galderma's patent rights--if the FDA approves the sale of Actavis's Adapalene Gel with instructions and labeling that will result in direct infringement of one or more claims of the '377 patent by users of Actavis's Adapalene Gel.

16. On information and belief, Actavis seeks approval of at least one indication for Actavis's Adapalene Gel that is claimed in the '377 patent.

17. On information and belief, Actavis knows that physicians will prescribe, and patients will use, Actavis's Adapalene Gel in accordance with the indication(s) sought by Actavis and will therefore infringe one or more claims of the '377 patent under 35 U.S.C. § 271(b) and/or (c).

18. Galderma will be substantially and irreparably harmed by Actavis's infringing activities unless those activities are enjoined by this Court. Galderma has no adequate remedy at law.

COUNT II FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '377 Patent Under 35 U.S.C. § 271(a)-(c))

19. Galderma realleges and incorporates by reference paragraphs 1-18.

20. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

21. The manufacture, sale, offer for sale, and/or importation of Actavis's Adapalene Gel, if approved by the FDA, will induce and contribute to infringement of one or more claims of the '377 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Galderma's patent rights.

22. On information and belief, if the FDA approves ANDA No. 201-000, Actavis or its agents plan to begin marketing, selling, and offering to sell Actavis's Adapalene Gel in the United States immediately or soon after receiving FDA approval for the indication(s) sought in ANDA No. 201-000.

23. Actavis's actions in actively aiding, abetting, encouraging, and inducing sales of Actavis's Adapalene Gel threaten to and will induce and/or contribute to infringement of one or more claims of the '377 patent in violation of Galderma's patent rights.

24. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Galderma and Actavis as to liability for the infringement of the '377 patent claims. Actavis's actions have created in Galderma a reasonable apprehension of irreparable harm and loss resulting from Actavis's threatened imminent actions.

COUNT III FOR PATENT INFRINGEMENT
(Infringement of the '181 Patent Under 35 U.S.C. § 271(e)(2))

25. Galderma realleges and incorporates by reference paragraphs 1-24.

26. The '181 patent, entitled "Pharmaceutical compositions comprising 0.3% by weight of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid for the treatment of dermatological disorders," was duly and legally issued to inventors Michael Graeber and Janusz

Czernielewski by the PTO on June 15, 2010. The '181 patent is currently owned by Galderma Research & Development, S.N.C., and expires on August 29, 2024. This expiration date includes a 536-day patent term adjustment granted by the PTO pursuant to 35 U.S.C. § 154(b). A true and correct copy of the '181 patent is attached as Exhibit C. A true and correct copy of the Issue Notification reflecting the '181 patent term adjustment is attached as Exhibit D.

27. The '181 patent is listed in the Orange Book for NDA No. 21-753.

28. On information and belief, ANDA No. 201-000 contains a Paragraph IV certification alleging the claims of the '181 patent are invalid, unenforceable and/or would not be infringed by the commercial manufacture, use, offer for sale or importation of the Actavis's Adapalene Gel prior to the expiration date of the '181 patent.

29. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Actavis sent or caused to be sent to Galderma the Notice Letter, which alleges that at least claims 2-28 and 30-34 of the '181 patent would not be infringed by Actavis's Adapalene Gel; and that at least claims 1, 29, 35, and 36 of the '181 patent are invalid.

30. Under 35 U.S.C. § 271(e)(2)(A), Actavis infringed one or more claims of the '181 patent, in violation of Galderma's patent rights, by submitting to the FDA an ANDA that seeks approval to commercially market--before the expiration date of the '181 patent--Actavis's Adapalene Gel, the manufacture, sale, or use of which would directly infringe one or more claims of the '181 patent.

31. Upon information and belief, Actavis has also induced or contributed to, and will induce or contribute to, infringement of one or more claims of the '181 patent--in violation of Galderma's patent rights--if the FDA approves the sale of Actavis's Adapalene Gel

with instructions and labeling that will result in direct infringement of one or more claims of the '181 patent by users of Actavis's Adapalene Gel.

32. On information and belief, Actavis knows that physicians will prescribe, and patients will use, Actavis's Adapalene Gel in accordance with the indications sought by Actavis and will infringe one or more claims of the '181 patent under 35 U.S.C. § 271(b) and/or (c).

33. Galderma will be substantially and irreparably harmed by Actavis's infringing activities unless those activities are enjoined by this Court. Galderma has no adequate remedy at law.

COUNT IV FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '181 Patent Under 35 U.S.C. § 271(a)-(c))

34. Galderma realleges and incorporates by reference paragraphs 1-33.

35. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

36. The manufacture, sale, offer for sale, and/or importation of Actavis's Adapalene Gel, if approved by the FDA, will directly infringe, and will induce and contribute to infringement of, one or more claims of the '181 patent under 35 U.S.C. § 271(a), (b) and/or (c), in violation of Galderma's patent rights.

37. Actavis's actions in actively aiding, abetting, encouraging, and inducing sales of Actavis's Adapalene Gel threaten to and will induce and/or contribute to infringement of one or more claims of the '181 patent in violation of Galderma's patent rights.

38. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Galderma and Actavis as to liability for the

infringement of the '181 patent claims. Actavis's actions have created in Galderma a reasonable apprehension of irreparable harm and loss resulting from Actavis's threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Galderma respectfully requests that this Court enter judgment in its favor as follows:

a) declare that, under 35 U.S.C. § 271(e)(2)(A), Actavis infringed the '377 patent by submitting ANDA No. 201-000 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Actavis's Adapalene Gel prior to the expiration of said patent;

b) declare that Actavis's commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Actavis's Adapalene Gel prior to the expiration of the '377 patent would constitute infringement of said patent in violation of Galderma's patent rights;

c) order that the effective date of any FDA approval of Actavis's Adapalene Gel shall be no earlier than the expiration date of the '377 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

d) enjoin Actavis, and all persons acting in concert with Actavis, from seeking, obtaining, or maintaining final approval of ANDA No. 201-000 until the expiration of the '377 patent;

e) enjoin Actavis, and all persons acting in concert with Actavis, from commercially manufacturing, using, offering for sale, or selling Actavis's Adapalene Gel within the United States, or importing Actavis's Adapalene Gel into the United States, until the expiration of the '377 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

f) declare that, under 35 U.S.C. § 271(e)(2)(A), Actavis infringed the '181 patent by submitting ANDA No. 201-000 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Actavis's Adapalene Gel prior to the expiration of the '181 patent;

g) declare that Actavis's commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Actavis's Adapalene Gel prior to the expiration of the '181 patent would constitute infringement of said patent in violation of Galderma's patent rights;

h) order that the effective date of any FDA approval of Actavis's Adapalene Gel shall be no earlier than the expiration date of the '181 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

i) enjoin Actavis, and all persons acting in concert with Actavis, from seeking, obtaining, or maintaining final approval of ANDA No. 201-000 until the expiration of the '181 patent;

j) enjoin Actavis, and all persons acting in concert with Actavis, from commercially manufacturing, using, offering for sale, or selling Actavis's Adapalene Gel within the United States, or importing Actavis's Adapalene Gel into the United States, until the expiration of the '181 patent, in accordance with 35 U.S.C. § 271(e)(4)(B); and

k) grant Galderma such further and additional relief that this Court deems just and proper.

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